

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

Civil Action No. 1:22-CV-00101

Wei Jiang, M.D)	
)	
Plaintiff,)	
)	
v.)	COMPLAINT
)	
Duke University, Duke University Health)	
System, Moira Rynn, M.D, in her)	(Jury Trial Demanded)
individual and official capacity, and Mary)	
E. Klotman, in her individual and official)	
capacity,)	
)	
Defendants.)	

NOW COMES Plaintiff, Wei Jiang, by and through the undersigned counsel and complaining of the Defendants, says as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiff under 42 U.S.C. § 1981 to correct unlawful and intentional employment practices including harassment, intentional discrimination, and retaliation by all of the Defendants against Plaintiff on the basis of Plaintiff's ancestry and ethnic characteristics, including her race, and to recover all damages permitted by law for the same.
2. This is an action by Plaintiff under 42 U.S.C. § 1985 to redress the injury

to Plaintiff resulting from the conspiracy between the individual Defendants and their agents and co-conspirators to deprive Plaintiff from enjoying the rights, privileges, and immunities of other physicians and researchers similarly situated to Plaintiff because of Plaintiff's race, national origin, ancestry, and ethnicity, (hereafter referred to as race and national origin) and to recover all damages permitted by law for the same.

3. This is also an action under Title VII of the Civil Rights Act of 1964, as amended, (42 U.S.C. § 2000e et seq.) to correct unlawful employment practices including harassment, discrimination, and retaliation by Defendant Duke University (Duke) and Defendant Duke University Health System (DUHS) against Plaintiff on the basis of her race, national origin, color, and sex, and to recover all damages permitted by law for the same, including punitive damages under § 1981(a).

4. This is also an action under the Age Discrimination in Employment Act, as amended, (ADEA”) (29 U.S.C. § 623 et seq.) to correct unlawful employment practices including harassment, discrimination, and retaliation by Defendant Duke and Defendant DUHS against Plaintiff on the basis of her age and to recover all damages permitted by law for the same.

PARTIES, JURISDICTION AND VENUE

5. Plaintiff was employed by Defendants Duke and DUHS at the time of the acts alleged in this Complaint.

6. Defendant Duke has been and is now a body politic and corporate, is capable of suing and being sued, and is located in Durham County, North Carolina. Duke employed Plaintiff at all relevant times in this Complaint.

7. Defendant DUHS has been and is a body politic and corporate, is capable of suing and being sued, and is located in Durham County, North Carolina. Along with Defendant Duke, DUHS was a joint employer of Plaintiff at all relevant times in this Complaint.

8. Defendant Moira Rynn (Rynn) has served as the chair of the Department of Psychiatry and Behavioral Sciences at Duke and working at DUHS since 2017 and served as Plaintiff's supervisor since that time.

9. Defendant Mary E. Klotman has served as the Dean of the Duke University Medical School since July 2017 and is thus responsible for the supervision and management of Defendant Rynn and Plaintiff.

10. This Court has jurisdiction over: Plaintiff's Title VII claim under 42 U.S.C. § 2000e5(f)(3) and 28 U.S.C. § 1331 and 42 U.S.C. § 1981a(a); Plaintiff's

ADEA claim under 28 U.S. C. § 1331; and over Plaintiff's §§ 1985 and 1981 claims under 28 U.S.C. §§ 1331 and 1343.

11. Venue is proper in this district in that the unlawful employment practices were committed in this district, the relevant employment records are maintained in this district, Defendants Duke and DUHS have their principal offices in this district, Defendants Rynn and Klotman and Plaintiff work in this district, and there is no other district that has substantial connection to the claim.

12. All conditions precedent to the institution of this lawsuit have been fulfilled, including the filing of a charge and the receipt of a right to sue letter from the Equal Employment Opportunity Commission.

STATEMENT OF FACTS

13. All allegations of each paragraph of this Complaint are incorporated into each Count thereof, as though fully set out therein.

14. Plaintiff was employed by Duke on Sept 1, 1989, as a Research Associate. She began a Formal Residency training on July 1, 1997, with the Duke Medicine & Psychiatry Combined Training Program. On July 1, 2002, she was hired at a salary of \$105,000.00.

15. Over the years, Plaintiff was consistently promoted, her salary increased every year (except 2012 due to university financial constraints), and she was eventually awarded tenure as a Full Professor in 2014.

16. From 2004 through 2017 Plaintiff took annual and sometimes bi-annual trips to China to collaborate with colleagues, provide mental health outreach and attend and present at conferences. She also visited with family on these trips.

17. As of 2017 Plaintiff was seeing patients but primarily was a researcher managing a laboratory at Duke and conducting clinical studies funded by grants from the National Institutes of Health (NIH) and the National Heart Lung and Blood Institute (NHLBI); these grants were for multiple years and funded a large portion of Plaintiff's salary. During her years of employment with Defendants, Plaintiff developed a strong reputation as a researcher, collaborator, and presenter.

18. From September 2006 to November 2011, Plaintiff worked primarily on the REMIT study (Responses of Myocardial Ischemia to Escitalopram Treatment) (ClinicalTrials.gov Identifier NCT00574847), funded by the NHLBI which was designed to study, as its name suggested, the effects of the

drug escitalopram on patients with myocardial ischemia (reduced blood flow to the heart which can result from conditions including mental or physical stress).

19. The earliest version of the study summarized the goal of the study as follows:

Brief Summary: Depression is commonly seen in patients with cardiovascular disorders, as in recent studies it has been shown that mild to moderate depression symptoms were associated with increased likelihood of mental stress-induced myocardial ischemia (MSIMI), which is a risk factor of poor cardiac outcome. In this project, we aim to assess the treatment of mental stress-induced myocardial ischemia in ischemic heart disease patients with mild to moderate depressive symptoms. This study is a six-week double-blind placebo-controlled study to examine the effects of escitalopram on **mental stress-induced myocardial ischemia**. This study will look to show that patients with ischemic heart disease who are treated with escitalopram will exhibit a significant improvement of **MSIMI** at the end of week 6 compared to patients receiving placebo.

Detailed Description: The goals of this project are to investigate the response of **mental stress-induced myocardial ischemia (MSIMI)** to escitalopram, an SSRI; to determine whether **MSIMI** will be reduced by the treatment, and whether the modification of **MSIMI** is related to improvement of depression symptoms, and/or to reduction of platelet aggregation, and/or to reduction of cardiovascular reactivity. This is a randomized study using escitalopram versus placebo for stable ischemic heart disease patients with **MSIMI**. This study will also explore the role of platelet activity in occurrence of **MSIMI** and other characteristics of **MSIMI**, such as systolic and diastolic function of the left ventricle during mental stress testing as comparing to exercise testing.

20. The final version was exactly the same but added one paragraph to the “detailed description”:

The stress testing will be conducted at the Duke Cardiology Diagnostic Unit Laboratory. Following a 20-minute calibration-rest period, participants will be asked to complete a series of 3 **mental stress** tasks. There are 3 mental stress tasks to be used for this study, i.e., (1) Mental arithmetic: during this test, patients will be asked to perform a series of serial subtractions beginning at a given number which will be different for each repeated test and will be chosen by the tester from a fixed list of various numbers, with encouragement to perform calculations as quickly as possible; (2) Public speaking with anger recall: during this test, patients will be asked to give a speech on a recent situation in which they experienced anger to an audience of observers (two to three) after 1 minute of preparation. Prior to the speech, subjects are told that their speech will be evaluated on their description of the situation, as to what happened, what they thought, felt, what they did, and what happened as a result. If they run out of things to say, the research tech will prompt them with questions to elicit more content until the three minutes are up; (3) Mirror trace: during this test, patients will be asked to outline, as quickly as possible, a star from its reflection in a mirror. Each task will last 3 minutes and there will be a 6-minute rest period between tasks.

21. The last version reported the outcome measures. The primary outcome measure listed (number 1) was entitled “Percentage of Participants With an Absence of **Mental Stress-induced Myocardial Ischemia (MSIMI)** During the 3 Mental Stressors.” Number 2 on the outcome measures, described as “primary,” was entitled “Percentage of Participants With Overall **Mental**

Stress-induced Myocardial Ischemia (MSIMI)."

22. Significantly, in version 9, the last version, outcome measures 3 – 14, were all labelled secondary outcomes and only the very last one, number 14, made any reference to "Exercise Stressed-induced Myocardial Ischemia (ESIMI)". Evaluation of ESIMI was not the primary focus of the REMIT study.

23. The REMIT study investigators published a paper in the American Heart Journal in 2012 describing the research methods for the study being conducted:

Substantially accumulated evidence demonstrates that transient emotional distress or **mental stress** is strongly linked to coronary heart disease (CHD).¹ Over the last couple of decades, the association of mental activity and myocardial ischemia has been well studied. **Mental stress-induced myocardial ischemia (MSIMI)** in the laboratory may occur in up to 70% in patients with clinically stable CHD² and is associated with increased death and cardiovascular (CV) events. Few studies have examined therapeutics that effectively modify **MSIMI**. We, therefore, are conducting a clinical trial, that is, the REMIT trial, to investigate whether selective serotonin reuptake inhibitor (SSRI) treatment can improve **MSIMI**. The methods and rationale of the study are described.

Clearly, and significantly, the focus of the study as described in this article was on **MSIMI**, not ESIMI.

24. The REMIT study investigators published a paper in 2013 in the Journal

of the American Medical Association (JAMA) in which they reported statistically significant results regarding **MSIMI** (more patients taking escitalopram had an absence of **MSIMI** during the 3 mental stressor tasks compared with patients taking the placebo) based on the unadjusted multiple imputation model for intention-to-treat analysis. The JAMA article also noted that rates of **ESIMI** were slightly lower in the escitalopram group than in the placebo group, but significantly acknowledged that the difference was not statistically significant.

25. A total of six papers were eventually written about the REMIT study and its conclusions. More papers could have been written but for Defendants' actions in sabotaging Plaintiff's research and publications career, as detailed herein.

BEGINNING OF THE AUDITS OF THE REMIT STUDY

26. After the JAMA publication in 2013, years passed.

27. On July 1, 2017, Defendant Rynn was hired to be the chair of the Department of Psychiatry and Behavioral Sciences. At his time, Plaintiff was earning over \$200,000.

28. Plaintiff's salary had consistently increased since her initial employment

with Defendants Duke and DUHS. Specifically:

DATE	SALARY
July 01, 2003	\$125,000.04
July 01, 2004	\$128,450.04
July 01, 2005	\$132,000.00
July 01, 2006	\$140,000.00
July 01, 2007	\$144,900.00
July 01, 2008	\$150,405.96
October 01, 2009	165,456.00
March 01, 2010	\$173,728.80
July 01, 2011	\$178,940.64
July 01, 2012	\$178,940.64
July 01, 2013	\$182,519.40
July 01, 2014	\$186,169.80
July 01, 2015	\$190,824.00
July 01, 2016	\$195,594.60
July 01, 2017	\$200,484.48

29. Defendant Rynn was selected as Chair of the Defendants Duke and DUHS Psychiatry and Behavioral Science department on July 1, 2017.

30. On April 18, 2018, Defendant Rynn requested an audit of the REMIT study for which Plaintiff was assigned as Principal Investigator.

31. As of July 1, 2018, Plaintiff's salary was reduced to \$152,629.92.

32. As of July 1, 2019, Plaintiff's salary was reduced to \$34,418.00, where it has remained since that time.

33. In the most three most recent annual appointment letters provided to Plaintiff by Defendant Rynn, Rynn had no discussion with Plaintiff as opposed to other faculty members similarly situated to Plaintiff.

34. The letters to Plaintiff stated only that Plaintiff would be working in a full professor position at an annual salary of \$34,418.00. A newly hired faculty with "instructor" position in 2020 earned an annual income of \$220,000.00. The difference in the salary paid to Plaintiff and the salary paid to other similarly situated individuals is attributable to discrimination based on Plaintiff's race, age, sex, and national origin.

EFFECTS OF DEFENDANT RYNN'S ANIMUS TOWARDS PLAINTIFF

35. Beginning in 2018, Defendant Rynn, with the oversight and approval of

Defendants DU and DUHS, began a campaign to disparage the REMIT study, and primarily Plaintiff's involvement in it as Principal (but not sole) Investigator. This disparagement was intended to cast doubt on Plaintiff's abilities to administer grants and serve as a principal investigator.

36. However, the scrutiny instigated by Defendant Rynn eventually turned into questioning the data analysis and conclusions reached in articles published not by just Plaintiff but co-authored by her co-investigators.

37. This scrutiny by Rynn and the other Defendants constituted discriminatory practices based on Plaintiff's race, sex, national origin, and age, and due to Rynn's professional jealousy of Plaintiff as an accomplished researcher and tenured professor, which Rynn was not.

38. Plaintiff was out of the country in April 2018. While travelling in China in April 2018, Plaintiff saw that Scott Kollins was stepping down as Vice Chair for Research and Plaintiff reached out to Defendant Rynn and expressed interest in the position.

39. At some point during the time Plaintiff was out of the country in China, Defendant Rynn instigated an internal review of the study files for the REMIT study. Rynn assigned Sharikia Burt, the Assistant Research Practice Manager,

to conduct the review. Burt began the study by scheduling an interview with Pamela Bonner, Plaintiff's research coordinator for her lab since 2017.

40. Unbeknownst to Plaintiff at the time, Rynn had called Bonner to her office to discuss Plaintiff's lab practices and thereafter used that meeting as a justification for beginning the multiple reviews that ensued into the REMIT study.

41. When Plaintiff returned to the country and to her office on April 25, 2018, she consulted with Dr. Jeannie Beckham about the reason for the departmental audit of the REMIT study which was by this time ongoing.

42. Beckham told Plaintiff that Pamela Bonner had made a complaint to Defendant Rynn alleging that Plaintiff did not know how to manage a laboratory. Plaintiff was shocked and wanted to reach out to Bonner, but Beckham instructed her not to discuss the matter with Bonner in order to not be viewed as retaliating against Bonner.

43. On April 30, 2018, Defendant Rynn requested a meeting with Plaintiff and indicated that she wanted to follow up the departmental audit with an audit by the university audit office. Rynn told Plaintiff that the audit would be a good way for Plaintiff to improve her research.

44. Plaintiff did not suspect any ill motives by Rynn at this time and although she did not understand why Rynn would want to revisit a study that had concluded in 2015, she did not oppose Rynn's desire to have the study audited past the departmental level. Rynn treated Plaintiff differently based on her race, sex, national origin, and age, and she instigated no other such audits of researchers similarly situated to Plaintiff.

45. Significantly, Plaintiff was provided no opportunity by Defendant Rynn to respond to the first Clinical Research Unit (CRU) report authored by Burt.

46. After her meeting with Plaintiff, Rynn then emailed Leigh Goller and David Falcone of the university Office of Audit, Risk, and Compliance (OARC) and indicated that Plaintiff and Rynn were requesting that the university audit the REMIT study.

47. After this email from Rynn, Falcone sent an email on May 1, 2018, asking Plaintiff or Rynn to call him, but later that day Rynn emailed Plaintiff and told her that there was no need for her to reach out and that Falcone had told her that his team would meet with her in 2-3 weeks.

48. Plaintiff would later observe, as the audits of the REMIT study continued, that Rynn would often essentially attempt to "run interference" and

prevent Plaintiff from contacting individuals who were involved in Rynn's efforts to discredit the REMIT study.

49. Also on May 1, 2018, as previously scheduled prior to Plaintiff's trip to China, Pamela Bonner left Plaintiff's lab.

50. On May 3, 2018, the departmental audit instigated by Defendant Rynn while Plaintiff was in China was completed and the report issued by Sharikia Burt stated that a departmental recommendation was being made to "escalate" the study "[d]ue to various issues observed during the QA review that may affect data integrity, subject safety and the concern for proper PI oversight."

51. Curiously, this report dated May 3, 2018, postdated Rynn's discussion with Plaintiff about elevating the audit of the REMIT study to the university audit office to which she attempted to get Plaintiff's consent. Thus, it appears that Rynn was managing the departmental audit report from behind the scenes and was successful in having included in the departmental study a recommendation to "escalate" the audit of the study to the university level.

52. The OARC Research Compliance Assurance (RCA) visited the research offices where the REMIT study records were kept between June 4-13 and July 3-7, 2018. They reviewed only 17 out of 310 subject study records initially and

then 8 more after initial review.

53. After the REMIT study, Plaintiff submitted another grant request to the NHLBI. NHLBI indicated in early July 2018, that it needed Plaintiff's response to the "just in time" (JIT)¹ document issued by agency. The departmental Clinical Research Unit (CRU) was responsible for providing the JIT response. The JIT eventually was prepared, but its delay caused significant tension.

54. Plaintiff reached out to Defendant Rynn and learned for the first time that Rynn had chosen not to fill the CRU director position or the Vice Chair for Research position about which Plaintiff had inquired in April. Instead, Rynn had decided that she would serve as the interim CRU director. Thus, the delay in getting the JIT document was the result of the fact that Scott Kollins had not been replaced as CRU head, which Plaintiff explained to the program officer at the NHLBI and copied Rynn in an email on August 21, 2018.

55. Rynn then scheduled a meeting with Plaintiff and Plaintiff learned that Rynn was going to supervise the CRU, and not replace Scott Kollins, and that she was offended by what she considered Plaintiff's criticism of the CRU's

¹ JIT documents are used by federal agencies to request pre-award materials that were not submitted as part of the original grant application.

failure to submit the JIT response to the NHLBI program officer.

56. On September 10, 2018, the Office of Audit, Research, and Compliance (OARC) Research Compliance Assurance (RCA) issued a report based on its review of 25 of the 310 subjects of the REMIT study and noted no significant patient safety concerns. Protocol and documentation concerns were noted, and the RCA recommended that Plaintiff and the study team submit the OARC report and Plaintiff's response to the university Institutional Review Board (IRB). The OARC also indicated that it had discussed the recommendations regarding protocols and "good clinical practices" (GCP) with both the IRB and the Duke Office of Clinical Research (DOCR) and the OARC was leaving implementation of its recommendations "to the discretion of the IRB and Psychiatry leadership."

57. The RCA recommended that the "IRB consult with a statistician to evaluate if and how data quality issues impact existing and future publications."

58. Meanwhile, the university OARC issued a report noting no patient safety concerns, but issues with protocol adherence. However, the protocol adherence issues turned out to be related to the exercise stress testing inclusion/exclusion

criteria, which was not the primary focus of the study; the primary focus of the study was mental stress IMI, not physical stress IMI.

59. In addition, the OARC RCA made recommendations for changes in the REMIT study, apparently unaware that the REMIT study had concluded more than three years prior to the OARC RCA's review and many of the recommendations could not be implemented retroactively but only prospectively in future studies.

60. On September 20, 2018, Bonner wrote Plaintiff asking her to be a reference for Bonner. Confused about why Bonner would want a reference from her if she believed that Plaintiff was a sub-par investigator, Plaintiff reached out to Bonner to schedule a meeting which occurred on September 24, 2018.

61. At this meeting, Bonner informed Plaintiff that she was called in to Defendant Rynn's office (the Department Chair) and Defendant Rynn "grilled" her for about an hour about the work done in Plaintiff's lab. Bonner told Plaintiff that she never stated that she had problems with Plaintiff's lab.

62. On September 25, the next day, Bonner wrote Plaintiff an email stating:

I'm sorry that you were told all these things and asked not to discuss them with me. I don't remember saying that I would not want to work with you again at that meeting, and I don't feel that way. Hopefully, we can keep our communication better in the

future. I know that I told them that I thought you were genuinely trying to follow the rules that you knew about and that it seemed like the issues that I had noticed were from no one telling the study team about evolving best practices. When asked about data integrity, I told them that I felt that your data could be trusted, that you have a great deal of personal integrity, and that any issues were only ones of documentation practices. I recommended more training for all the CRCs in the department and more guidance/support for the principal investigators. I did recommend that they give you an experienced CRC to work with in the future if you were funded for your study. I hope that you still feel good about me after all this hearsay, and I do hope for the best for your new projects moving forward.

63. Defendant Rynn's pretextual reliance on Bonner's complaints as a basis for the reason for auditing the REMIT study thus became obvious and Plaintiff became aware that Defendant Rynn was treating her differently from other researchers and physicians based on her race, sex, national origin, and age. Rynn instigated no other such audits of researchers similarly situated to Plaintiff.

64. On the same day that Plaintiff met with Bonner, she learned that her grant for NHLBI project R01, R01HL140060 designed to examine "Mental Stress-Induced Left Ventricular Dysfunction and Mitochondrial Dysfunction in Women" was awarded for a period for 4 years. On Plaintiff's original proposal. The initial year alone was funded at almost \$800,000.00.

65. Between October 4 and November 1, 2018, Plaintiff travelled to China on an outreach trip and to visit her family.

66. The OARC RCA report was submitted to the IRB on November 26, 2018, and evaluated by the IRB on December 19, 2018. The IRB concluded that there the report did not show any Involving Risk to Subjects or Others (UPIRTSO). The IRB concurred with OARC recommendations, presumably made with regard to prospective studies given that the REMIT study had long concluded. As to the REMIT study, the IRB stated it wanted to see independent expert opinion on the “interpretation of the stress tests, ECHOs and how the ineligible patients were handled in the reporting of the data.” The IRB stated that the **“PI and Investigators, with the support of the CRU and School of Medicine, should seek independent expert opinion on these issues and report back to the Board with their conclusions.”**

67. Despite this IRB request, not only did Defendant Rynn not support the acquisition of an independent expert to resolve any outstanding issues about the REMIT study, but instead Defendant Rynn instigated a second departmental Clinical Research Unit review of the REMIT study, decidedly not independent, and focusing on the inclusion/exclusion criteria applied to 127 of

the original 307 patients who completed the REMIT baseline screening and were found to have met the “eligibility criteria” for the study.

68. Again, Defendant Rynn’s scrutiny of Plaintiff’s involvement in the REMIT study in which many other researchers were involved centered on Plaintiff. It was obvious to Plaintiff that Rynn was treating Plaintiff differently based on her race, sex, national origin, and age, and she instigated no other such audits of researchers similarly situated to Plaintiff nor did she attempt to involve any of the other white and male physicians in the audit process or ask them for their responses to the questions that she was raising.

69. The CRU review was conducted by Terry Ainsworth, Director of Research in the DOCR; Alifia Hasan, the departmental research practice manager for the Psychiatry department; and Scott Compton, who had been selected by Defendant Rynn finally to become the Director of the Psychiatry CRU.

70. The CRU focused primarily on exclusion criteria originally related to patient safety concerns:

Table 2. A Summary of the Number of Participants that Failed by Eligibility Criteria		
Eligibility Criteria	Number of Participants	Participant IDs
EC 1	N = 1	090-024

Table 2. A Summary of the Number of Participants that Failed by Eligibility Criteria		
Eligibility Criteria	Number of Participants	Participant IDs
Recent myocardial infarction, coronary artery bypass graft surgery, or other revascularization procedures (>3 months)		
EC 4 Unable to withdraw from anti-anginal medications during ischemic assessment phase	N = 10	161-049; 175-054; 206-066; 233-077; 235-080; 238-082; 264-089; 299-098; 310-105; 358-115
EC 5 Unable to perform exercise testing	N = 6	020-004; 046-016; 102-029; 180-051; 236-081; 377-121
EC 6 Pregnancy	N = 3	109-033; 319-103; 379-122
EC 10 Significant cardiac, pulmonary, metabolic,	N = 1	025-012

Table 2. A Summary of the Number of Participants that Failed by Eligibility Criteria

Eligibility Criteria	Number of Participants	Participant IDs
renal, hepatic disease, or malignancy, interfering with patient's participation in this study		
EC 12 currently taking anti-depressants that can not be discontinued	N = 1	144-042
IC 3.1 and EC 4 <i>(IC dropped as of 10/2008)</i> and Unable to withdraw from anti-anginal medications during ischemic assessment phase	N = 1	015-003
EC 4 and EC 5 Unable to withdraw from anti-anginal medications during ischemic assessment phase and Unable to perform exercise	N = 2	268-093; 284-095

Table 2. A Summary of the Number of Participants that Failed by Eligibility Criteria		
Eligibility Criteria	Number of Participants	Participant IDs
testing		
EC 6 and EC 12 Pregnancy & currently taking anti-depressants that can not be discontinued	N = 1	265-090

71. EC 4 (unable to withdraw from anti-anginal medications) and EC 12 (currently taking anti-depressants that cannot be discontinued) were waived for 15 study participants to allow the study participants to safely continue participation in the study. Because the study evaluated patients at baseline on medication and then at the conclusion of the study on the same medication, waiving these exclusions had no effect on the study's conclusions about mental stress IMI.

72. EC 5 (unable to perform exercise testing) was also waived for six participants to allow the study participants to safely continue participation in the study. In addition, because exercise stress IMI was not a primary focus of the study, waiving this exclusion criterion has no effect on the conclusions

about MSIMI.

73. One patient was allowed to participate despite his undergoing a cardio-diagnostic cardiac catheterization on June 30, 2008, because he had chest pain symptoms. The patient was found to have no acute myocardial infarction. He had no re-vascularization and was found to have normal LV function. Ultimately, his cardiologist informed the REMIT study investigators, which included cardiologists, that the patient's IHD was stable and he agreed to have the patient enrolled in the REMIT study. Thus, there was no patient safety concern.

74. One participant in the study was not excluded because 6 days after baseline testing he was ultimately diagnosed with a "significant cardiac, pulmonary, metabolic, renal, hepatic disease, or malignancy, interfering with patient's participation in this study" (EC 10), that diagnosis did not occur until after baseline testing and randomization to the REMIT intervention and there was no evidence that he had cancer prior to a dizziness episode which occurred after randomization.

75. Again, most of the questions about the inclusion and exclusion criteria related to the cardiovascular health of the patients. Instead of consulting with

the cardiologists' investigators on this study, Defendant Rynn attempted to hold Plaintiff responsible and treated her differently because Rynn treated Plaintiff differently because of her race, sex, national origin, and age.

76. On January 7, 2019, Plaintiff met with Defendant Rynn and suggested that because the new grant also involved cardiologists that the grant might be better supervised out of the cardiology department. Rynn apparently perceiving this as a threat, then threatened to terminate the grant under her authority as Department chair.

77. At this same time, Plaintiff sought again to obtain CRU and departmental support for complying with the IRB request that the Plaintiff and her Investigators, with the support of the CRU and School of Medicine, seek "an independent expert opinion on these issues and report back to the Board with their conclusions." Rynn held Plaintiff responsible for the entire conduct of the study and all decisions made with regard to the study, as opposed to addressing issues to all of the investigators or allowing Plaintiff to do so.

78. Rynn instigated no other reviews of any other researchers in the Psychiatry and Behavioral Sciences department and no other studies were

initiated against other researchers similarly situated to Plaintiff.

79. Scott Compton told Plaintiff he would reach out to the IRB about whether a random sample of the ECHOs and exercise stress tests could be evaluated and relayed on January 9, 2020, that Jody Power with the IRB had said that a random sample would be fine,^b but that a “deeper dive” might be required at some point.

80. Plaintiff then told Compton that she was going to confer with her co-investigators as directed by the IRB. Compton then sent Plaintiff an email copying Defendant Rynn stating that “Moira expressly asked that we not discuss the audit with anyone outside of Duke. . . . Based upon this request, I think it would not be prudent to inform the cardiologists at this point in time.” Defendant Rynn responded to the email stating: “That is correct, Scott, no one has my permission to share any information pertaining to this audit outside of our group. Thanks, Moira.”

81. Plaintiff then wrote an email to both Compton and Defendant Rynn stating:

having a hard time comprehending why I cannot communicate with the co-investigators of REMIT about the audit. They have been working with us for many years and have made unique contributions to REMIT study. From the Echo standpoint, as the

PI of REMIT, except for outlining guidelines, I have no role in the REMIT echo quality and interpretation process. I feel that it would be respectful to my echo-cardiology collaborative colleagues, who reviewed all the REMIT echo images, that their echo ratings will be re-examined. Dr. Eric Velazquez and Dr. Zainab Samad are very well known echo-cardiologists who have had top level echo training. They also have enriched experience in analyzing mental stress induced cardiac echo images. I think they may have adjunct positions with Duke after they moved to Chairs of Medicine in different institutions. I sincerely think they need to be informed of the decision to re-read the echo images.

Moving forward, I would like to make a suggestion. Given the nature of cardiac echo imaging study and the unique hemodynamic impact of mental stress on cardiovascular system, it would be a good idea to have echo-cardiologists who have had comparable training and experience with mental stress testing to do the required re-rating.

Plaintiff received no response to this email and ultimately Defendant Rynn obtained cardiologists untrained in the research protocol to conduct what she ultimately submitted to the IRB as “expert” and independent opinions on the REMIT study. This was a further manifestation of Rynn’s treating Plaintiff different than other similarly situated researchers based on her sex, race, age, and national origin.

82. Meanwhile, the second CRU report instigated by Defendant Rynn was sent to the IRB on January 18, 2019. This time, Plaintiff was given an opportunity to provide her response to the report and she did.

CANCELLATION OF PLAINTIFF'S RO1 GRANT

83. In a shocking escalation of the hostile work environment to which Plaintiff had been subjected, on January 23, 2019, at a meeting with Plaintiff and Geeta Swamy, Defendant Rynn informed Plaintiff that in her capacity as Department Chair, Rynn had decided to terminate Plaintiff's grant which had been awarded in the Fall of 2018. Notably, the reasons given for the cancellation of this grant were pretext for Rynn's age, sex, race, and national origin discrimination against Plaintiff.

84. This grant had a first-year value of almost \$800,000 and would have provided valuable research as well as financial support for Plaintiff's career.

85. This termination occurred in complete non-compliance with the IRB procedures for terminating previously approved research protocols. This termination was an adverse action clearly based on Plaintiff's race, sex, age, and national origin, was unprecedented, and another example of how Plaintiff was treated differently from other researchers who were similarly situated to her except as to race, sex, age, and national origin.

86. Upon information and belief, no other IRB approved protocols have been terminated in the same manner as Plaintiff's and she was singled out by

Defendant Rynn and treated differently based on Plaintiff's race, sex, national origin, and age.

87. Despite Plaintiff's protests, Swamy told Plaintiff that she would compose a letter to NHLBI for the termination and would share the letter with Plaintiff prior to submitting it to the NIH system, which Swamy did not do, again treating Plaintiff differently based on her race, sex, age, and national origin.

88. Defendant Rynn's termination of Plaintiff's new R01 negatively impacted the professional career of Plaintiff and several of her colleagues. It negatively impacted Plaintiff's professional reputation, and significantly Plaintiff's financial support, given that 30-50% of Plaintiff's university salary would have been covered for at least five years by this grant.

89. Despite being told that Defendant Rynn had terminated her grant, Plaintiff continued to receive messages from the NHLBI concerning her need to complete activities consistent with the grant being active. To address these emails, on April 19, 2019, Plaintiff wrote to Dr. Swamy, who had indicated previously on January 23, 2019, that she would provide Plaintiff Jiang with correspondence to NIH regarding the termination of the grant.

Dear Dr. Swamy,

May you please verify the relinquishment of my new R01(R01 HL140060) for us? I have not seen the letter or report to NIH that you said you would share with me during our meeting on 01/23/19. Dr. Compton, the Psychiatry department CRU director, has verbally informed me that the termination of the R01 has been formal. However, I continue receiving notifications from NHLBI regarding activities that I, the PI of the project, need to address, and reminder that I am late in responding to those requirements. I did not respond because I have been following the guidance of our CRU that we not communicate with NHLBI regarding this matter. I view having a formal notification of the R01 relinquishment is necessary for our record keeping.

Best, Jan

90. Significantly, Dr. Swamy replied on April 25, 2019:

Jan,

Thank you for your email and my apologies in not responding to you sooner. Please see the attached documentation that Duke has relinquished the grant. As we discussed previously and is stated in the Duke Faculty Handbook (appendix P, page 41), faculty are not permitted to communicate with external sponsors on administrative issues. We also discussed that you would like to speak with your program officer, Catherine Stoney, about your continued interest in the research from a scientific perspective. You may do that but only with someone from your department/CRU leadership or School of Medicine Leadership included on the phone call with you. I have copied Scott and Moira on this email so that you may work with them to determine next steps and who to include on such a call if you would like to proceed with that plan.

Thanks, Geeta

91. This email provided Plaintiff with no documentation regarding

Defendant Rynn's cancellation of her grant, and also with further evidence of Defendant Rynn's attempts, through Dr. Swamy, to continue Defendant Rynn's efforts to insulate Plaintiff Jiang from having any contact with anyone who could question or oppose Defendant Rynn's discriminatory and retaliatory treatment of Plaintiff Jiang. Again, this was discriminatory treatment based on Plaintiff's age, sex, race, and national origin.

92. Eventually Plaintiff learned that Michael Dickman had sent an email to Christina Rinaldi at the NIH/NHLBI on March 6, 2019, stating that the University wanted to "initiate the process" for relinquishing the first-year budget award of \$799,690.00 to the U.S. Department of Health and Human Services, Public Health Service 1R01-HL140060-01A1.

CONTINUED HOSTILITIES BY DEFENDANT RYNN

93. Also, not content to sabotage her research career in the United States, Defendant Rynn then informed Plaintiff that she would not be allowed to take her April trip to China due to the need for her to stay at Duke in case she needed to address issues emerging from the audits. At this point, the IRB had directed an independent expert review which would not have involved Plaintiff.

94. On January 30, 2019, the IRB had issued a “Notice of Review of Safety Event” and stated that upon review of the CRU report and presumably Plaintiff’s response, the IRB “declared that the problem/event does not represent an Unanticipated Problem Involving Risk to Subject or Others (UPIRTSO). No further action is required.” Thus, there was no action to be taken by Plaintiff with regard to the second CRU report.

95. On February 22, 2019, Plaintiff wrote an email to Defendant Rynn imploring her to reconsider forbidding Plaintiff to travel to China in which she stated:

I established my academic commitment to China in 2003. I have set up two primary goals to achieve in China this year, one is to enhance the understanding and resolving the fear and fear related symptoms emerging from significant physical events, and the other is to make the team approach in health provision more comprehensive and accepted in medical practice in China. You may find the topic of my formal talk in the April international CV conference (Formal invitation attached) of interest. I have also attached for you a brief description of why implementing mental health and integrated care is particularly important.

To accommodate your requirements, I am willing to reduce my trip to no more than 10 work-days and have also taken an extra week of inpatient service in April 2019. I highly appreciate your re-consideration and approval of my trip to China, so I can have an uninterrupted academic practice there.

96. Defendant Rynn then scheduled a meeting with Plaintiff to discuss a “clinical matter” and also “to review your academic and clinical financial support.”

97. Plaintiff was concerned and asked the Faculty Ombudsman to attend the meeting, Dr. Tom Metzloff. At first Rynn refused to let him attend. Eventually, after discussion of the clinical matter, she then permitted him to come into the meeting.

98. The remainder of the meeting, about 40 minutes, involved Defendant Rynn reiterating that for Plaintiff’s sake, she could not allow Plaintiff to leave Duke Campus because Plaintiff might need to respond to questions about the REMIT study. During the meeting, Defendant Rynn became more and more restless and irritable when both Dr. Metzloff and Plaintiff offered that the department CRU director Scott Compton had indicated that Plaintiff could respond via electronic communication. At one point, Defendant Rynn accused Plaintiff of being too calm, and stated that if she were Plaintiff, she would be anxiously staying at Duke, not going anywhere else.

99. After the meeting, Dr. Metzloff offered to Plaintiff that it might ease the obviously hostile behavior of Defendant Rynn towards Plaintiff if Plaintiff were

to agree not to go to China. Plaintiff reluctantly agreed.

100. In fact, during the time period Plaintiff would have been in China, there were no face-to-face interactions required about any matter related to the REMIT study.

**FALSE ALLEGATIONS OF RESEARCH MISCONDUCT INVOLVING
THE REMIT STUDY MADE TO US DHHS**

101. Undaunted by the IRB's lack of concern with the exclusion criteria applied in the REMIT study and determined to destroy Plaintiff's research and career, and unsatisfied with having cancelled her outreach trip to China, Defendant Rynn, upon information and belief, either made or caused to be, made an accusation of research misconduct involved the REMIT study to the U.S. Department of Health and Human Services (US DHHS) Office of Research Integrity (ORI).

102. As a result of the accusation, on March 4, 2019, the US DHHS ORI Research Integrity Officer (RIOO) then requested that Defendants "conduct an inquiry into allegations of possible falsification of the REMIT clinical research records. The purpose of the inquiry would be to determine if there were evidence of potential research misconduct that would warrant an investigation. The inquiry will be conducted by members of our Standing

Committee on Misconduct in Research (SCMR).” Plaintiff learned of this next step from Donna Kessler on March 11, 2019, when she was informed that the US DHHS requested inquiry into “research misconduct” would be referred to the university’s Standing Committee on Misconduct in Research (SCMR).

103. Unbeknownst to Plaintiff at the time, despite her inquiries about her grant, on March 6, 2019, an email was sent from Michael Dickman with the Duke Office of Research Administration to Christina Rinaldi, National Institute of Health (NIH) representing that Duke University wished to relinquish the funds associated with the new five-year grant awarded to Plaintiff Jiang. On that same date, the remaining funds for the first year of the public health service research grant terminated by Defendant Rynn (\$799,690.00) were returned to US DHHS, Public Health Service.

104. The SCMR interviewed Dr. Stephen Boyle, Plaintiff Jiang’s co-author on the REMIT study publications, on May 21, 2019. Plaintiff Jiang was interviewed by the Committee on June 17, 2019. On July 15, 2019, the SCMR interviewed Jennifer Wilson, who had served as one of the REMIT Study coordinators, of which there were several, including Pamela Bonner.

105. On October 22, 2019, the SCRM issued a report concluding that no

research misconduct had occurred.

106. However, the SCMR went well beyond its sole charge to investigate whether research misconduct occurred and included information in its report about “protocol deviations.” In fact, the REMIT study had IRB approved protocols for every year in which patients were enrolled. Nonetheless, the SCMR determined that protocol deviations had occurred and made several recommendations again, wholly outside the scope of their authority.

DENIALS OF TRANSFER

107. While the SCMR was investigating research misconduct, on July 12, 2019, Plaintiff learned about a School of Medicine/Duke Health position for Assistant Director positions to work with the new Center for Interprofessional Education and Care which was created to expand opportunities for learners and clinicians throughout the health system to enhance their skills in interprofessional practice, working with the Center Director Mitch Heflin (Dr. Heflin), and focusing on the areas of preclinical and clinical education, faculty development, evaluation and scholarship. The announcement also indicated that applications required a cover letter summarizing interest, a copy of the applicant’s curriculum vitae, and most significantly for Plaintiff, a letter of

support from the applicant's department chair, division, or program head, attesting to the applicant's qualifications and their support for the applicant's time, which was estimated to be one day a week.

108. Plaintiff Jiang reached out on July 15, 2019, to Jeannie Beckham and Defendant Rynn regarding Plaintiff Jiang's interest in the position and asking for their support for her application.

109. Plaintiff Jiang also reached out on July 16, 2019, by email to Dr. Heflin, the Center Director and contact for the position, and expressed her interest and asked whether there were funds available to cover the time spent in the position because her chief wanted to know. Dr. Heflin replied that there were funds available.

110. Defendant Rynn did not respond to Plaintiff Jiang's email until July 23, at which point she indicated that she wanted to set up a meeting to discuss the matter of Plaintiff Jiang's application. Plaintiff Jiang met with Defendant Rynn and Jean Beckham, and they declined to support her application for the position.

111. On July 31, 2019, Plaintiff Jiang wrote an email to Defendant Rynn to summarize the discussions at the meeting which included both Plaintiff Jiang's

proposed Fall trip to China and the School of Medicine position:

Dear Moira,

Thank you for taking time to meet me.

I would like to summarize what I have learned from you at the meeting.

1. Re: My application request to response to the call of the Duke IPEC

I heard from you that you have reached out to the Duke IPEC and learned that the program is looking for individuals who have had a high volume of outpatient services. Such individual will be in leadership of leading IP outpatient service. You have discussed with Dr. Shirey (may be others that I could not recall names) and made your nominations to IPEC. You will not make any new nominations for the AD position of the Duke IPEC. It is your opinion that I am not at the level of the IPEC is looking for.

2. My visit to my mother in China in the fall

You gave me your support for it, provided that I work out with Dr. Holmer for not having conflict on inpatient service.

Best, Jan

112. Rynn then responded to Plaintiff Jiang's email:

Yes, reached out to SOM and Drs. Holmer and Heilbron for appropriate nominations who stressed the importance of leadership experience of a multi-discipline professional team and strong communication skills.

And if we could please have your vacation dates that you plan to

take. Thanks, Moira

113. Because Defendant Rynn refused to support Plaintiff Jiang's application for the position, Plaintiff Jiang then reached out to Dr. Heflin to communicate Defendant Rynn's decision not to support Plaintiff Jiang's application.

Defendant Rynn informed me that she has reached out to SOM and Drs. Holmer (Psychiatry inpatient service director) and Heilbron (Psychiatry department vice Chair for clinics) for appropriate nominations who stressed the importance of leadership experience of a multi-discipline professional team and strong communication skills. Dr. Rynn learned that your IPEC program is looking for individuals who have had a high volume of outpatient services. Such individual will be in leadership of leading IP outpatient service. Dr. Rynn has made her nominations to IPEC and will not make any new nominations for the AD position of the Duke IPEC. Dr. Rynn thinks I am not at the level of the IPEC is looking for.

Best, Jan

114. Dr. Heflin replied that Dr. Rynn was mistaken that there was a preference for individuals with a high volume of outpatient services and that he would be happy to answer any questions for Dr. Rynn. Plaintiff Jiang considered whether it would be worthwhile for Dr. Heflin to reach out to Defendant Rynn but decided against doing so as it was clear to Plaintiff Jiang that Defendant Rynn would not support her no matter. Feeling discouraged and victimized by Defendant Rynn's bullying over the months since the audit

commenced and Defendant Rynn unilaterally cancelled her five-year grant, Plaintiff Jiang engaged in introspection about the matter and determined to pose a direct inquiry to Defendant Rynn about Plaintiff Jiang's status at Duke.

115. In October, another opportunity involving executive leadership in academic medicine (ELAM) became posted and once again Plaintiff Jiang discussed with her chair, Defendant Rynn, and sought her support per the job announcement. In a curt, one sentence response, Defendant Rynn replied: At this point in time, I am unable to support your application for this program. Dr Jiang sought an explanation: "That's disappointing. I'd highly appreciate if you may provide me the reason(s) underlying your decision. Jan" the same day and again, Defendant Rynn's reply was curt and lacked any substantive information: "It is based upon the issues we have already discussed."

CONFIRMATION OF THE CONTINUOUS HOSTILE WORK ENVIRONMENT

116. On August 2, 2019, Plaintiff wrote Defendant Rynn an email stating:

Dear Moira,

In thinking about our recent conversations, it appears that my role as a tenured, full Professor in our Department has changed significantly over the past year. I need you to clarify your position regarding several recurring issues that we have discussed over the past several months:

1. My research activities: It is my understanding that you have forbid[den] me from conducting any research in which I am a principal investigator. This restriction includes my examining data from previous studies, writing manuscripts, and applying for new funding from the NIH, industry, or other funding sources. Am I correct that this is your position, and if it is, when can I expect this restriction to be lifted?
2. My international collaborations: It is my understanding that you are not permitting me to pursue my ongoing collaborations with my longtime Chinese colleagues, including not allowing me to travel to China or developing a formal contract with academic centers in China. If this is correct, please provide me with an explanation for your position and an indication of under what circumstances will this restriction be lifted.
3. My professional activities: It is my understanding that you want to limit my professional activities to the inpatient service and to supervise and train residents and medical students on the inpatient service. Is this correct?
4. My new R-01 grant that's relinquished: It was my understanding at the meeting with you and Dr. Swamy that Dr. Swamy planned to compose a letter to NHLBI with reason(s) for the relinquishment. She would share the letter with me prior to communicate with NHLBI for the action. You did not think that was what Dr. Swamy meant.

To make sure there is no misunderstanding, I would appreciate your confirming that this is how you have defined my role in the Department at this time and what I can expect going forward. Thank you for taking the time to respond to my request.

Sincerely, Wei Jiang

117. On August 9, 2019, Defendant Rynn responded:

Dear Jan,

Thank you for your most recent email, although I will say that I was surprised to again see questions listed that we have provided answers to in multiple previous communications.

To summarize, the research audit that remains underway regarding your studies is a serious matter and we appreciate your attention and full participation with of our colleagues in the School of Medicine who are working on our behalf to understand and guide us through the next steps. At this time, as the audits are underway, I am putting your approved research activities on hold, to include the submission of new awards. The findings to date clearly outline the need for additional training and resources to enable you to begin to work in research at the highest level of integrity and quality. As a senior faculty member and PI, I expect you to understand and recognize the importance of this support that the Department is providing to you at this time. I also remind you that the NIH and other federal agencies hold Duke – as well as the PI – responsible for adherence to quality.

The expectations for a senior level hospitalist provider are clear and consistent across our PDC provider group. I do understand you are scheduled to work and support patient care services across Duke Health inpatient services this fiscal year. In addition, again consistent with our training programs within the Department of Psychiatry, providers are expected and encouraged to work/teach trainees of all levels in their specific work setting.

Lastly Jan, I do understand that this has been a terribly stressful time and I will again share that the senior leadership team for Research and the Chair's office, along with our partners across the School of Medicine, are working in your long-term interest as we

take the necessary steps to demonstrate your ability to conduct quality research.

I do not at this time approve professional requests for extended travel that takes you from our clinical operational needs here at Duke, as well as the audit process related to your research program.

All faculty have the same access to vacation and extended leave requests in accordance with the faculty handbook, <https://provost.duke.edu/sites/all/files/FHB.pdf>. According to the handbook, faculty with twelve-month appointments in the Medical Center have compensation that covers eleven months of effort and one month of paid vacation. One month of paid vacation is equal to 22 business days and PDC vacation policy. Please review these resources to determine any further leave at this time. Division Director approval is required for any extended leave related to FMLA etc.

Thanks again Jan for your continued participation in the research inquiry and follow-up. We appreciate all that you do to support our patients and trainees across our inpatient services. We will continue to be in touch regarding feedback on research review.

Moirra

IRB REQUESTED RE-EVALUATION BY INDEPENDENT EXPERTS AND SCMR INQUIRY

118. At the same time as the SCMR inquiry prompted by a report of alleged research misconduct involving the REMIT study, Plaintiff was unable to move forward with her co-investigators to obtain the “independent” and “expert” opinion requested by the IRB in December 2018.

119. However, on March 25, 2019, the SCMR initiated a re-evaluation (re-reads) of echocardiograms from the REMIT study by Dr. Pam Douglas with the Duke Clinical Research Institute.

120. In addition, on April 11, 2019, the SCMR initiated a statistical re-analysis of the primary REMIT study outcomes provided in the 2013 JAMA publication of the study results.

121. Previously, Defendant Rynn had commissioned Susanna Stevens and Lilin She to evaluate the REMIT data conclusions in the JAMA article published by Plaintiff and her co-investigators. In an email on March 8, 2019, Dr. She stated the following:

As the first step, Susanna and I have tried to replicate a few key numbers for the primary results published in JAMA using the same patient population and the same datasets and programs sent to DCRI. We can replicate some of the numbers but cannot replicate some others. Overall, our numbers are very close to what were published. If we have more time, we would like to investigate further on why we could not match 100% with the JAMA paper.

As the second step, we also re-ran the SAS programs after excluding those 26 subjects who are considered as not eligible according to the recent assessment. The results are slightly changed. You can review the differences in the attached tables. Since we now have a smaller sample size, the p-values are changed. However, the results obtained from this reduced patient sample are in general very similar to the results published in JAMA.

122. This email was not shared with Plaintiff at the time, and she only learned of it later and not from Defendant Rynn.

123. After Plaintiff learned that the SCMR had initiated in April 2019 a re-evaluation of the echocardiograms conducted during the study between 2006 and 2015 by Pam Douglas and the apparent presumption that there were “ineligible subjects,” she scheduled a meeting with Paul Lantos, Jody Power, and Walter Lee, members of the Duke IRB, to discuss Plaintiff Jiang’s concerns regarding the SCMR’s draft conclusions.

124. Plaintiff expressed her concern about the potential determination that there were “ineligible subjects” and fact that re-calculations were being done of the statistical analysis using numbers different from those used by the investigators who conducted the study.

125. In addition, Plaintiff also expressed her concern about the analysis of the echocardiograms re-read by Pam Douglas, M.D. because she did not have the same training as the cardiologists who served as co-investigators with Plaintiff.

126. At the meeting, Jody Power, Duke IRB Chair, denied making any comment about needing to “dive deeper” (in REMIT) to Scott Compton or

anyone.

127. Plaintiff Jiang sent a follow up email after the September 12, 2019, meeting on September 30, thanking them for meeting and inquiring about the IRB review and consideration of the SCMR inquiry. Dr. Lantos responded on October 6 and confirmed understanding of Plaintiff Jiang's concerns about the application of principles recently developed to work done during the REMIT study. Significantly, he assured Plaintiff Jiang that they would not "reevaluate 2006 science using 2019 eyes."

Hi Jan,

Thanks again for coming over to meet us. We certainly heard and acknowledge your concern about whether a reevaluation of the echo data from the REMIT study might cast doubt on your findings primarily due to advances in echocardiography in the years since REMIT was done.

We hopefully provided some reassurance that this would be an unlikely outcome, as our goal is not to reevaluate 2006 science using 2019 eyes. There is really a spectrum of outcomes, with the extremes being that an audit fully confirms the original findings or it's completely incompatible with them. In between these two there could certainly be a gray area in which the original findings would be seen as reasonable. If it happens that the audit finds major fault with the original findings, I can't imagine that this would lead to a summary judgment or action without first diving deeper into these findings, and certainly making sure you and your collaborators aware.

I believe that was the understanding we reached during the meeting. Please let me know if there is anything you believe I missed.

128. Plaintiff Jiang wrote back and thanked him and expressed encouragement. She also expressed that the audit had been ongoing for over a year and that she had been forbidden to publish manuscripts or doing research and she had been prevented from sharing her thoughts and concerns about the audit.

Dear Paul,

Thank you very much for your message summarizing the key element we discussed during our meeting. I am particularly impressed by your comment that “our goal is not to reevaluate 2006 science using 2019 eyes”. My perception for the “Our” is that it means Duke IRB. Please clarify if my perception is wrong.

I am much encouraged and confident now regarding the continued REMIT audit that has been happening for more than a year and remains being open ended. With it, I have been forbidden to publish several manuscripts produced from the REMIT biomarker study and been forbidden from doing research as PI. I have not given any permission to share my thoughts/concerns for certain issues in the REMIT audit.

I would like to ask you all to provide me update, if possible, on what further evaluation you are doing before I receive the final conclusion of the REMIT audit.

Sincerely,

Best, Jan

129. Prior to the release of the final report, and when it became aware that the IRB was going to consider the SCMR report, Plaintiff contacted Donna Kessler on October 16, 2019, and expressed concern that “independent and expert” evaluations had not been obtained as requested by the IRB. Plaintiff also expressed concerns she, Plaintiff Jiang, as the principal investigator, and her co-investigators, Dr. O’Connor, Dr. Velazquez, and Dr. Samad, had not been allowed to obtain “independent expert opinion on these issues and report back to the Board with their conclusion.” Finally, Plaintiff expressed concerns that she and her co- investigators were completely cut out of the process of obtaining independent and expert options and that Dr. Douglas was selected presumably by Defendant Rynn or others at her behest to do the analysis.

130. Plaintiff also told Kessler that the two echo-cardiologists who analyzed the REMIT echo images originally had been trained on how to analyze REMIT echo images. In addition, they analyzed all the images consensually whereas Dr. Douglas only re-read a proportion of REMIT echo images for unclear reasons, and there is no indication that she read the images in consultation with any colleagues, and certainly not with any colleagues trained in this area. Finally, Dr. Douglas provided no explanation as to how she produced the EF

scores she included in her evaluation. In fact, the echo-cardiology lab which did the original reading used software to analyze the REMIT echo images and produce the original EF scores and the REMIT cardiologists validated these measurements.

131. As for the actual design of the study which Dr. Douglas criticized, in fact, the REMIT study was designed between 2003 and 2006 and used the best methods at that time relating to when and how the echocardiogram should be utilized in mental stress and exercise stress testing. Dr. Douglas' evaluation in March 2019 imposed her opinion of 2019 design standards on a study designed more than ten years prior.

132. Finally, Dr. Douglas failed to perform a thorough evaluation on the REMIT echo images in that she did not re-read for the eligible participants both baseline and endpoint mental stress echocardiograms for the same participants. Instead, she only re-read a randomized sample of individuals with baseline results and a different randomized sample of individuals with endpoint results. Despite Dr. Douglas' failure to re-read consistently both of baseline and endpoint echocardiograms for a randomized group of participants who had both baseline and endpoint echocardiograms, she provided a

statistical analysis to support her conclusions in paragraph 9 regarding percentages of “agreement” with the original REMIT study findings concerning both baseline and endpoint assessments.

133. O’Connor, Velazquez, and Samad had reviewed the re-evaluation of the echocardiograms and concluded that they were flawed, and Plaintiff Jiang also raised this issue with Donna Kessler as well, prior to the release date of the report on October 22, 2019.

134. Nonetheless, on October 22, 2019, the Duke Standing Committee on Research Misconduct (SCRM) was issued and concluded that there was no evidence of falsification or fabrication of study records. The report again noted that the beta blocker and exercise stress testing amendments from the original protocol and again alleged they were not communicated to the IRB as required. But significantly, no new information was provided by the SCRM inquiry.

135. Despite having concluded that there was no research misconduct, which should have been the end of the inquiry of the SCMR, the SCMR nonetheless recommended:

1. The managing editors of the 2012 Am. Heart J. (Jiang et al.) and 2013 JAMA (Jiang et al.) publications should be contacted with the known information about the reporting of the REMIT study conduct and results to determine if

corrections and/or retractions may be needed.

2. The Department/CRU, along with Plaintiff Jiang and the applicable co- authors, should review the other REMIT study publications to determine whether the research is accurately represented in those publications or if the managing editors of the journals should be contacted about possible corrections or retractions.
3. Plaintiff Jiang should attend a robust workshop on Good Clinical Practice and the requirements of clinical research equivalent to what would be needed to obtain certification as a Certified Principal Investigator or Certified Clinical Research Professional . . .
4. If Plaintiff Jiang will be applying for future federal funding to conduct research, she should attend the Responsible Conduct of Research Short Course conducted by the Trent Center for Bioethics or an equivalent program.

136. Plaintiff Jiang was already scheduled to take personal leave, and not scholarly leave, to visit China to do outreach and visit her family because of Defendant Rynn's refusal to approve scholarly leave (in an email on August 9, 2019). Thus, Plaintiff was in China from October 17 to November 22, 2019, and thus on the date that the final SCMR report was issued.

137. Plaintiff Jiang was offered the opportunity to provide a response to the SCMR report by December 6, 2019, but given her trip and her other work expectations, on November 12, 2019, Plaintiff Jiang requested an extension

due to her need to carefully consider the report, given that over a year had been spent between the OARC and the SCMR investigations/inquiries, and also due to the fact that while in China, Plaintiff Jiang was having to care for her 87-year old mother who had become critically ill.

138. On November 13, 2019, Donna Kessler, Duke Research Integrity Officer, replied to Plaintiff Jiang's request for an extension and denied it, stating that the University's response from the Dean Mary Klotman was due to the US DHHS Office of Research Integrity (ORI) by December 5th. Dr. Kessler did not apparently consider whether the University could or should request an extension of time due to Plaintiff Jiang's request. Kessler then reiterated Plaintiff Jiang's deadline of November 18 to get her comments to Dr. Klotman for a final submission on December 5, 2019.

139. On November 15, Plaintiff Jiang then reiterated an earlier question that she had made regarding the Echo re-read matter previously raised and included in the SCRM report and again questioned the source of the allegations made to the US DHHS / NIH Research Integrity Office about research misconduct. On the same day, Kessler replied but did not identify the source of the allegations made about research misconduct.

DEAN RECOMMENDATIONS

140. As a result of the SCMR report and the false conclusions about noncompliance with IRB approved protocols, Defendant Klotman then wrote Plaintiff on November 22, 2019, prior to responding to the US DHHS regarding the allegations of research misconduct. In her letter Defendant Klotman agreed with the SCMR conclusion that confirmed insufficient evidence of research misconduct and agree with the additional corrective actions recommended by the SCMR. Dean Klotman stated she would consider Plaintiff Jiang's response to the SCMR report to be provided by December 5, 2019.

141. On November 26, Plaintiff Jiang conferred with the Duke IRB chair Paul Lantos and also with Ombudsman Thomas Metzloff regarding Plaintiff Jiang's desire to consult with the original REMIT cardiology co-investigators / collaborators who provided the original cardiology and statistical analysis for the original study due to their expertise in echocardiography. Dr. Lantos emailed her and indicated that he "wanted to confirm, having spoken with Jody, that the IRB would like the cardiologists who were on your study to have the opportunity to review and respond to the echo audit, even if they are no longer at Duke." Plaintiff Jiang had explained that Defendant Rynn had

previously instructed her NOT to reach out to the original team who worked on the study because they were no longer at Duke. In fact, when Plaintiff had raised the issue with the IRB about Defendant Rynn's forbidding her to contact her co-investigators about the re-evaluation of the REMIT study, Paul Lantos had responded as follows:

My personal point of view is you did your science as a team and it should be the team that responds to an audit or investigation, especially for something like echo interpretation or statistics for which you have coinvestigators who are experts.

I do not think we as the IRB have any authority to tell you whom you can or can't consult with, nor do we have the authority to override instructions from others to NOT speak with anyone. Tom will be able to answer this better than I, but I'm not sure you can really be prohibited from speaking with someone unless it's on the advice of Duke counsel or it's a case of protected information that can't be shared. It's worth contesting any instructions you've gotten to not speak with your collaborators if you feel they are unfair or against policy.

142. On December 12, 2019, the Duke IRB was provided a copy of the OARC report and reviewed the same on December 19, 2019, to determine whether the event represented an Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO). Having concluded it did not, on December 26, the Duke IRB issued a notice of review stating that no UPIRTSO had occurred and that further reiterating that the "PI and Investigators, with the support of the CRU

and School of Medicine, should seek independent expert opinion on these issues and report back to the Board with their conclusions.”

143. Notwithstanding the Dean’s recommendations that the SCMR recommendations be implement, in January 2020, Defendant Rynn then imposed draconian sanctions which had the effect of ending Plaintiff’s research career completely.

144. On January 29, 2020, Defendant Rynn admitted to Plaintiff Jiang that she had instigated all of the reviews and audits even though she never believed that Plaintiff or her co-investigators had engaged in any research misconduct.

145. At this same meeting, Plaintiff Jiang then informed Defendant Rynn that she had a research support fund of \$48,847.00 with the Behavioral Medicine Research Center (BMRC). Defendant Rynn then informed Plaintiff Jiang that she could not use that money for her salary support.

146. Although the BMRC had previously been led by Dr. Redford Williams, Plaintiff Jiang was aware that Defendant Rynn had removed Dr. Williams from the directorship sometime in middle of 2019 and had herself has been serving the interim director of the BMRC since doing so.

147. Furthermore, Plaintiff Jiang had a \$20,805.40 fund for mental health

outreach in her own discretionary account, but since March 2019, Defendant Rynn had forbidden Plaintiff Jiang to leave the Duke campus for any academic activities, such that this money was also unavailable to her.

148. In April 2020, Plaintiff appealed to Defendant Klotman who informed Plaintiff on May 29, 2020, that she supported

the decision of Defendant Rynn to implement more restrictive corrective actions based on the totality of information available to her regarding your work within the Department. The corrective actions you outline from my November 22, 2019 letter to Donna Kessler are based solely on the recommendations provided by the Standing Committee on Misconduct in Research. The corrective actions outlined in my November 22, 2019 letter do not take into account other audits, reviews, or information known to the Department at the time Dr. Rynn made her decision.

149. Despite inquiry by Plaintiff, neither Defendant Klotman nor Defendant Rynn ever identified the additional “totality of the information” nor “other audits, reviews, or information known to the Department” at the time Defendant Rynn imposed her more severe sanctions.

ADDITIONAL SCRUTINY OF PLAINTIFF BASED ON HER NATIONAL ORIGIN / RACE

150. On December 18, 2018, Geeta Swamy sent Plaintiff an email stating:

The SOM is wanting to get a full understanding of your most recent trip to China- what was the nature of the trip- was there any funding provided to Jan – including the cost of her travels

etc. The SoM has recently received a letter from NIH regarding a PI in another Department who failed to note that he had collaborated internationally with China etc. Geeta and team remembered that you had recently traveled and wanted to find out the details of the trip to be sure we don't need to disclose anything on her behalf.

151. On February 25, 2019, Jiang received email messages from her department CRU and the Duke Office of Scientific Integrity - COI Faculty Correspondence, asking her:

Lindsey Spangler, from Research Facilitation, has reached out to me to make sure that you contact COI regarding your travels to China. She wanted to make sure that you have reported these activities correctly. Can you please promptly reach out to them and let us know when this has been completed. The Duke COI office can be reached at (919) 684-312.

152. During this period of time, Defendant Rynn refused Plaintiff's requests to received funding from sources in China which would have provided financial support for Plaintiff's mental health outreach in China.

153. Defendants discriminated against Plaintiff by denying her funds and the opportunity to engage in mental health outreach in China based on her national origin, race, sex, and age.

**ADDITIONAL ATTEMPTS TO PROFESSIONALLY DEFAME
PLAINTIFF AND SABOTAGE HER REPUTATION**

154. Again, not content with destroying Plaintiff's career, in 2021, Defendant

Rynn instructed Scott Compton to correspond with the editor of JAMA to cast doubt on the science behind the article published by Plaintiff and her co-investigators.

155. With the assistance of counsel, Plaintiff was able to withstand Defendants' attempts to have JAMA retract the article and further efforts to discredit the REMIT study have so far been rebuffed.

COUNT ONE: TITLE VII AND ADEA
RACE, COLOR, AGE, AND SEX DISCRIMINATION
IN VIOLATION AGAINST DEFENDANTS DUKE AND DUHS

15. Plaintiff is female, of the Chinese race and older than 40.

16. Plaintiff is a member of several protected classes and was qualified for her position when she was subjected to a hostile work environment, and discriminated against and retaliated against because of her age, sex, race, and national origin.

17. Defendants collectively and individually have ruined her reputation as a researcher and constructively terminated her employment.

18. Plaintiff's supervisor, Defendant Rynn, regularly bullied Plaintiff and marginalized her by misleading Plaintiff and others and encouraging the belief in findings and reports that were biased, erroneous, and tainted by personal

animus.

19. Plaintiff has suffered damages as a result of Defendant's unlawful discriminatory actions, including emotional distress, past and future lost wages and benefits, and the costs of bringing this action.

20. Defendant intentionally violated Plaintiff's rights under Title VII and the ADEA, with malice or reckless indifference, and, as a result, is liable for punitive damages.

COUNT TWO: RACE DISCRIMINATION AND RETALIATION
SECTIONS 1981 AGAINST DEFENDANT RYNN AND DEFENDANT
KLOTMAN IN HER INDIVIDUAL CAPACITY

21. Plaintiff Jiang's race and national origin is Asian (Chinese).

22. Defendant Rynn threatened and bullied Plaintiff and treated other non-Asian and White employees more favorably.

23. Defendants Klotman, Duke and DUHS facilitated and approved of Defendant Rynn's treatment of Plaintiff.

24. Plaintiff suffered damages due to Defendants unlawful discriminatory and retaliatory actions, including emotional distress, past and future lost wages and benefits, and the costs of bringing this action.

25. Defendant intentionally violated Plaintiff's rights under section 1981

with malice or reckless indifference, and, as a result, is liable for punitive damages.

**COUNT THREE: CONSPIRACY TO ENGAGE IN A DEPRIVATION
OF CIVIL RIGHTS BASED ON RACE, SEX, NATIONAL ORIGIN, AND
AGE BY ALL DEFENDANTS AGAINST PLAINTIFF**

26. Plaintiff Jiang's race and national origin is Asian (Chinese), and she is female and over 40.

27. Defendant Rynn threatened and bullied Plaintiff and treated other younger, non-Asian and White employees more favorably.

28. Defendants Klotman, Duke and DUHS facilitated and approved of Defendant Rynn's treatment of Plaintiff.

29. Plaintiff suffered damages due to Defendants unlawful discriminatory and retaliatory actions, including emotional distress, past and future lost wages and benefits, and the costs of bringing this action.

30. Defendant intentionally violated Plaintiff's rights under section 1985 with malice or reckless indifference, and, as a result, is liable for punitive damages.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff respectfully prays that this Court:

1. Issue an injunction directing the Defendants to restore Plaintiff's previous status;
2. That this Court enjoin the Defendants from discriminating on the basis on race, color, sex and age in the terms and conditions of employment;
3. That this Court order Defendants to make whole Plaintiff by providing her with appropriate lost earnings and other lost benefits, with prejudgment interest, in amounts to be proved at trial, and other affirmative relief necessary to eradicate the effects of its unlawful employment practices, including, but not limited to, reinstatement to her previous salary and restoration of the amounts she has lost in research funding as a result of Defendants' actions;
4. That this Court order Defendants to make whole Plaintiff by providing compensation for nonpecuniary losses, including emotional pain, suffering, inconvenience, and mental anguish in amounts to be proven at trial;
5. That this Court order Defendant Duke to institute and carry out policies, practices, and programs which provide equal opportunities to qualified individuals, and which eradicate the effects of past and present unlawful practices;
6. That this Court award the Plaintiff reasonable attorney's fees and the

other costs of this action;

7. That this Court award Plaintiff such other and further relief as may be just and equitable.

JURY TRIAL DEMANDED

Plaintiff requests a jury trial on all questions of fact raised by the Complaint.

Respectfully submitted, this the 26th day of November 2021.

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